



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/552,089 | 10/04/2005 | Joachim Hoernes | ROCHE-P003 | 4169 |
| 63049 7590 08/18/2009 BAKER & DANIELS LLP / ROCHE 300 NORTH MERIDIAN STREET SUITE 2700 INDIANAPOLIS, IN 46204 | | | | |
| EXAMINER | | | | |
| OMCBA, ESSAMA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3726 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 08/18/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,089

Applicant(s)

HOENES ET AL.

Examiner

Essama Omgba

Art Unit

3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2-10, 12-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al. (US 2002/0168290) in view of Kuhr et al. (US Patent 7,396,334).

With regards to claims 18 and 21, Yuzhakov et al. discloses a method for producing combined puncturing and measuring devices for detection of an analyte in liquid comprising a support 8 and a detection element 12 (see abstract and paragraph [0010]), the method comprising forming recesses (spaces between elements 212 in figure 6A) which define puncturing points 212 on one face of a band shape support material, applying a detection element 206, and separating individual puncturing/measuring disposable bodies singly from the band-shaped support material at separating lines (fig. 6A and paragraph [0108]. Although Yuzhakov et al. does not explicitly disclose sterilizing the puncturing points and/or the band-shaped support material, however it is known to sterilize puncturing points of lancet devices at the time of manufacture as attested by Kuhr et al., see column 8, lines 54-62 and column 9, lines 10-11. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have sterilized the puncturing and measuring devices of

Yuzhakov et al., in light of the teachings of Kuhr et al., in order to prevent infection during puncturing of the skin.

Regarding claim 2, see channel 238.

Regarding claims 3-5, see figures 6A-6C.

Regarding claim 6, see channel 238 and paragraph [0082].

Regarding claims 7 and 8, Official Notice is taken in that depressions with a depression base which has a triangular contour are old and well known in the art, as is forming depressions by punching or cutting out material

Regarding claim 9, see figure 6A.

Regarding claim 10, Applicant should note that it is conventional to ground such puncturing points.

Regarding claims 12, 13 and 16, see paragraph [0082].

Regarding claims 14, 15 and 17, see figure 6A.

Regarding claim 20, applicant should note that the channels in the method of Yuzhakov et al. can be produced by embossing.

3. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al./Kuhr et al. as applied to claims 18 and 21 above, and further in view of Schenk et al. (US Patent 5,397,334).

Yuzhakov et al./Kuhr et al. discloses a method for producing combined puncturing and measuring devices as shown above including a detection device applied to the puncturing/measuring bodies after the puncturing and measuring devices have been sterilized (col. 8, lines 54-62 of Kuhr et al.). Although Yuzhakov et al./Kuhr et al.

does not explicitly disclose providing a soft plastic cover on the puncturing points of the puncturing devices, however it is known to cover the puncturing points of such devices with a soft plastic cover in order to preserve the sterility of the puncturing points as attested by Schenk et al., see column 1, lines 54-61 and column 5, lines 31-35.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided a soft plastic cover on the puncturing point of the device of Yuzhakov et al./Kuhr et al., in light of the teachings of Schenk et al., in order to preserve the sterility of the puncturing point.

Response to Arguments

4. Applicant's arguments filed May 26, 2009 have been fully considered but they are not persuasive.

In response to Applicant's argument that Yuzhakov et al. does not disclose sterilizing the puncturing points, the examiner submits that it is known to sterilize puncturing points of lancet devices at the time of manufacture as attested by Kuhr et al. or Schenk et al.

5. Applicant's arguments with respect to claim 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Essama Omgba whose telephone number is (571) 272-4532. The examiner can normally be reached on M-F 9-6:30, 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on (571) 272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Essama Omgba/
Primary Examiner, Art Unit 3726

eo
August 15, 2009